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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,396	12/08/1998	JAN HOLGERSSON	45115-53906	3163

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	18

DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/194,396	Applicant(s) Holgersson et al.
	Examiner G. R. Ewoldt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 28, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-28* is/are pending in the application.

4a) Of the above, claim(s) *27* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *21-26 and 28* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The request filed on 8/28/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/194,396 is acceptable and a CPA has been established. An action on the CPA follows.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 21-26 and 28, drawn to a dimerized fusion protein, classified in Class 424, subclasses 134.1 and 137.1 and Class 530, subclasses 387.3.

II. Claim 27, drawn to a method of treating a hyperacute rejection reaction, classified in Class 424, subclass 140.1.

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the fusion proteins of Group I can alternatively be used as antigens for antibody generation or for *in vitro* assays.

4. During a telephone conversation with Ivor Elrifi on 9/17/01, Applicant indicated that should a restriction election be required, Applicant would elect the Group comprising the fusion protein product. Affirmation of this election must be made by Applicant in replying to this Office action. Claim 27 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 21-26 and 28 are being acted upon.

5. In view of Applicant's amendment and response, including the cancellation of all pending claims and the submission of new claims, filed 8/28/01, all previous rejections have been withdrawn.

6. The following are New Grounds of Rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 21-26 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "at least a region of a P-selectin glycoprotein ligand-1 ... at least a region of an immunoglobulin polypeptide," (Claim 21),

B) "an extracellular portion of a P-selectin glycoprotein ligand-1 ..." (Claim 24),

C) "a region of a heavy chain immunoglobulin polypeptide." (Claim 25),

D) "The fusion protein of Claim 21, wherein the first polypeptide comprises more Galα1,3Gal epitopes than a wild-type P-selectin glycoprotein ligand-1." (Claim 28).

Applicant's amendment, filed 8/28/01, asserts that no new matter has been added, however, the cited passages on pages 4 and 5 of the specification do not provide specific support for the newly claimed limitations.

9. Claims 21-26 and 28 are rejected under 35 U.S.C.§ 112, first paragraph, because the specification, while being enabling for:

a dimerized fusion protein comprising a PSGL-1 and an immunoglobulin Fc region,

does not reasonably provide enablement for:

a dimerized fusion protein comprising at least a region of a PSGL-1 and at least a region of an immunoglobulin polypeptide.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Regarding "at least a region," the specification fails to disclose a definition for "at least a region." Therefore, said "regions" must be considered to encompass an essentially unlimited number of fragments as small as single amino acids. As such, the claimed "protein" would be considered highly unpredictable as single amino acid fragments would be unlikely to function as absorbers of pre-existing human antibodies, given the well-known requirement that an antibody epitope comprise at least 5 or 6 amino acids as well as the well-known biochemical fact that only certain amino acids can be glycosylated, i.e., asparagine, serine, threonine, or hydroxylysine. Given said unpredictability, the claimed invention would require undue experimentation in practicing its intended use.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of working examples employing fusion proteins comprising only "a region" of PSGL-1 and an IgFc region, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
November 15, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
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